K000741

OCT 2 4 2001

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

138 Medical Supplies Inc.
313 Butler Street
Brooklyn, NY 11217

Date Summary Prepared:

February 1, 2000
Contact: Ms. Isabelle Liang

2. Name of the Device:

EMS Jumper II Dual Channel Neuromuscular Stimulation System,
Model E-188

3. Predicate Device Information:

K# 951951, K# 864010, EMPI Respond Select II Powered Muscle Stimulator (NMES), EMPI, Inc., 5255 East River Road, Fridley, MN 55421

4. Device Description:

The EMS Jumper II is used a dual channel NMES device that produces a mild electrical current that is transmitted via leads to electrodes placed on the skin in areas predetermined by the clinician. The device, a set of electrodes with their lead wires, and batteries (3 AA alkaline) make up the EMS Jumper II Neuromuscular Stimulation System. Channel 1 and Channel 2 are independently adjustable from 0 to 100 mA using alkaline batteries and the output waveform is asymmetrical biphasic.

5. Intended Use:

As an NMES device, the Jumper II is indicated for the following conditions:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical simulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion

6. Comparison to Predicate Devices:

The EMS Jumper II Dual Channel Neuromuscular Stimulation System, Model E-188 unit is substantially equivalent to the EMPI Respond Select II Powered Muscle Stimulator.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

All required sections of the FDA "Guidance Document for Powered Muscle Stimulator 510(k)'s" were met. All required IEC 60601-1 and IEC 60601-1-2 testing was met.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The EMS Jumper II Dual Channel Neuromuscular Stimulation System, Model E-188 has the same intended use and technological characteristics as the EMPI Respond Select II Powered Muscle Stimulator device. Moreover, bench testing contained in this submission supplied demonstrate that technological characteristics do not raise any new questions of safety or effectiveness. Thus, the EMS Jumper II Dual Channel Neuromuscular Stimulation System, Model E-188 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2001

Mrs. Susan D. Goldstein-Falk
138 Medical Supplies, Inc.
313 Butler Street
Brooklyn, NY 11217

Re: K000741
Trade/Device Name: EMS Jumper II, Model E-188
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Codes: IPF
Dated: July 24, 2001
Received: July 26, 2001

Dear Mrs. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K000741

Device Name: EMS Jumper II Dual Channel Neuromuscular Stimulation System, Model E-188

Indications For Use:

As an NMES device, the Jumper II is indicated for the following conditions:

1. Relaxation of muscle spasms;
2. Prevention or retardation of disuse atrophy;
3. Increasing local blood circulation;
4. Muscle re-education;
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion.

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K000741

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **(Per 21 CFR 801.109)** **OR** **Over-The-Counter Use** ____ **(Optional Format 1-2-96)**